K080686

APR 22 2008

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Westcon Horizon™ 49 (hioxifilcon B)
Soft Contact Lens for Daily Wear

I. Submitter Information

510(k) Owner:
Westcon Contact Lens Company.
611 Eisenhauer Street
Grand Junction, CO 81505

510(k) Preparer & Contact Person:
Kevin Randall
GlobalReg™ Compliance Associates, Inc.
581 Whiles Court
Erie, CO 80516-7225
Phone: 303-828-0844
Fax: 303-828-0835
Email:kevin@globalregcompliance.com
www.globalregcompliance.com

Date Summary Prepared:
February 29, 2008

II. Name of Device

* Trade Name: Westcon Horizon™ 49 (hioxifilcon B)
* Common Name: Daily Wear Soft Contact Lens
* Classification Name: Lenses, Soft Contact, Daily Wear
* USAN (generic name): (hioxifilcon B)

III. Predicate Devices

Subject Device	Predicate Device(s)
Westcon Horizon™ 49 **(hioxifilcon B)**	Horizon™59 (hioxifilcon A) **(K043540)**
	Benz-G 3X (hioxifilcon B) Spherical and Toric Soft (Hydrophilic) Contact Lenses for Daily Wear in Clear and with a Blue Visibility Tint **(K964528)**

IV. Device Description & Technological Characteristics

The Westcon Horizon™ 49 (hioxifilcon B) soft contact lenses for daily wear that are manufactured from hioxifilcon B lens blanks are lathe cut into a hemispherical shell that are designed to fit over the corneal surface of the eye. These lenses are

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designed with varying base curves that conform to the shape of the radius of the cornea and center over the apex of the cornea to provide correction of refractive ametropia (myopia, hyperopic, astigmatism and presbyopia) in aphakic and not-aphakic persons with non-diseased eyes.

The non-ionic lens material, **hioxifilcon B**, is a copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydrosypropyl Methacrylate (Glycerol Methacrylate, GMA). It consists of 52% hioxifilcon B and 48% water by weight when immersed in normal saline solution buffered with sodium bicarbonate. The Westcon Horizon™ 49 (hioxifilcon B) is made out of hioxifilcon B and is available in clear and with a blue visibility-handling tint, phthalocyanato (2) – (copper). This is a legally marketed color additive for which FDA has previously reviewed the toxicology/biocompatibility profile [see the Toxicology / Biocompatibility section of this submission for further data regarding phthalocyanato (2) – (copper)].

Horizon™ 49 (hioxifilcon B) Spherical, Horizon™ 49 (hioxifilcon B) Toric, Horizon™ 49 (hioxifilcon B) Bi-con, Horizon™ 49 (hioxifilcon B) Bi-con Toric, Horizon™ 49 (hioxifilcon B) Progressive, Horizon™ 49 (hioxifilcon B) Progressive Toric for daily wear are indicated for the correction of refractive ametropia (myopia, hyperopic, astigmatism and presbyopia) in aphakic and not-aphakic persons with non-diseased eyes.

The physical properties of the **hioxifilcon B** lens are:

Refractive Index	1.425 (hydrated)
Light Transmission (clear)	greater than 95% T
Light Transmission (tinted)	greater than 95% T
Water Content	48 %
Specific Gravity	1.136 (hydrated)
Oxygen Permeability	15×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (revised Fatt method).

The Westcon Horizon™ 49 (hioxifilcon B) is a lathe-cut soft lens. In the dry (unhydrated) state the lens is machined and polished. In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. In the hydrated state, the Westcon Horizon™ 49 (hioxifilcon B), when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

The progressive optics in the Horizon™ 49 progressive designs utilize the simultaneous vision concept which offers functional vision from distance to near throughout the viewing range. The pupil zone on the front surface varies with the size of the patient's pupil.

V. Intended Use

Horizon™ 49 (hioxifilcon B) Spherical, Horizon™ 49 (hioxifilcon B) Toric, Horizon™ 49 (hioxifilcon B) Bi-con, Horizon™ 49 (hioxifilcon B) Bi-con Toric, Horizon™ 49 (hioxifilcon B) Progressive, Horizon™ 49 (hioxifilcon B) Progressive Toric for daily wear are indicated for the correction of refractive ametropia (myopia, hyperopic, astigmatism and presbyopia) in aphakic and not-aphakic persons with non-diseased eyes.

The lenses may be disinfected using chemical systems only.

VI. Pre-Clinical Performance Data

Pre-clinical performance data can be referenced for hioxifilcon B in Benz Research and Development's 510(k) K964528.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 2008

Westcon Contact Lens Company
c/o Kevin Randall
GlobalReg™ Compliance Associates, Inc.
581 Whiles Court
Erie, CO 80516-7225

Re: K080686
Trade/Device Name: Westcon Horizon™ 49 (hioxifilcon B)
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: January 31, 2008
Received: March 11, 2008

Dear Mr. Randall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K080686

Device Name:

Westcon Horizon™ 49 (hioxifilcon B)

Indications For Use:

Horizon™ 49 (hioxifilcon B) **Spherical,** Horizon™ 49 (hioxifilcon B) **Toric,** Horizon™ 49 (hioxifilcon B) **Bi-con,** Horizon™ 49 (hioxifilcon B) **Bi-con Toric,** Horizon™ 49 (hioxifilcon B) **Progressive,** Horizon™ 49 (hioxifilcon B) **Progressive Toric** for daily wear are indicated for the correction of refractive ametropia (myopia, hyperopic, astigmatism and presbyopia) in aphakic and not-aphakic persons with non-diseased eyes.

The lenses may be disinfected using chemical systems only.

PLEASE DO NOT WRITE BELOW THIS LINE
CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K080686

Prescription Use X **OR** **Over-The-Counter Use** _____

(Optional Format 1-2-96)